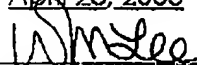


Patent Docket P1467R2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of Camellia W. Adams et al. Serial No.: 09/602,812 Filed: June 23, 2000 For: Humanized Anti-ErbB2 Antibodies and Treatment with Anti-ErbB2 Antibodies	Group Art Unit: 1642 Examiner: Anne Holleran <hr/> Certificate of Mailing Delivery I hereby certify that this correspondence is being hand delivered to the US Patent and Trademark Office on <u>April 28, 2003</u>  Wendy M. Lee
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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
 Assistant Commissioner of Patents
 Washington, D.C. 20231



Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached revised Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This Information Disclosure Statement is filed in accordance with the provisions of:

☐ **37 CFR §1.97(b)**

- within three months of the filing date of the application other than a continued prosecution application under 37 CFR §1.53(d); or
- within three months of the date of entry of the national stage of a PCT application as set forth in 37 CFR §1.491, or
- before the mailing of the first Office action on the merits; or
- before the mailing of the first Office action after the filing of a request for a continued examination under 37 CFR §1.114.

☒ **37 CFR §1.97(c)**

- by the applicant after the period specified in 37 CFR §1.97(b), but prior to the mailing date of any of a final action under 37 CFR §1.113, or a notice of allowance under 37 CFR §1.311, or an action that otherwise closes prosecution in the application, and is accompanied by either the fee set forth in 37 CFR §1.17(p) or a statement as specified in 37 CFR §1.97(e), as checked below.

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☐ **37 CFR §1.97(d)**

- after the period specified in CFR § 1.97(c), and is accompanied by the fee set forth in 37 CFR § 1.17(p) and a statement as specified in 37 CFR § 1.97(e), as checked below.

[If either of boxes 37 CFR § 1.97(c) or 37 CFR § 1.97(d) is checked above, the following statement under 37 CFR § 1.97(e) may need to be completed.]

- ☐ **37 CFR §1.97(e)** Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ **37 CFR §1.704(d)** Each item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application and the communication was not received by any individual designated in §1.56(c) more than thirty days prior to the filing of this information disclosure statement. Therefore, in accordance with the provisions of 37 CFR § 1.704(d), the filing of this information disclosure statement will not be considered a failure to engage in reasonable efforts to conclude prosecution under 37 CFR § 1.704.
- ☒ The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$180.00 to cover the cost of this Information Disclosure Statement under 37 CFR § 1.17(p). Any deficiency or overpayment should be charged or credited to this deposit account.

A list of the patent(s) or publication(s) is set forth on the attached revised Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith.

Those patent(s) or publication(s) which are marked with an asterisk (*) in the attached PTO-1449 form are not supplied.

☐ **BLAST results enclosed:**

The undersigned also wishes to bring to the attention of the Examiner BLAST results of computerized alignments of the against sequences contained in the nucleotide and protein databases. The BLAST results are provided in paper form and are identified as reference "BLAST Results A-1 - A-()" (nucleotide) and "BLAST Results B-1 - B-()" (protein) on the PTO Form 1449. Applicant requests that these references also be considered and that the Form 1449 be initialed to indicate the Examiner's consideration of the references.

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A concise explanation of relevance of the items listed on PTO-1449 is:

☒ not given

☐ given for each listed item

☐ given for only non-English language listed item(s) [Required]

☐ in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

In accordance with 37 CFR § 1.97(g), the filing of this information disclosure statement shall not be construed as a representation that a search has been made.

In accordance with 37 CFR § 1.97(h), the filing of this information disclosure statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 CFR § 1.56(b).

The Commissioner is hereby authorized to charge any additional fees required under 37 CFR 1.16 and 1.17 for this Information Disclosure Statement, or credit overpayment to Deposit Account No. 07-0630. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

GENENTECH, INC.

Date: April 28, 2003

By: Wm Lee

Wendy Lee

Reg. No. 40,378

Telephone No. (650) 225-1994



09157

PATENT TRADEMARK OFFICE

FORM PTO-1449 LIST OF DISCLOSURES CITED BY APPLICANT (Use several sheets if necessary)		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1467R2	Serial No. 09/602,812
				Applicant Adams et al.	
				Filing Date 23 Jun 2000	
				Group 1642	

U.S. PATENT DOCUMENTS							
Examiner Initials	Document Number	Date	Name	Class	Subclass	Filing Date	
	236	2002/0076695	Ross, J.				
	237	2002/0155527	Stuart et al.				
	238	5,514,554	Bacus, S.				
	239	5,571,894	Wels, W. et al.				
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	241	5,783,404	Koski, R.				
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	243	5,856,089	Wang et al.				
	244	5,882,864	An et al.				
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	246	5,994,071	Ross et al.				
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	248	6,333,348	Vogel et al.				
	249	6,358,682	Jaffee et al.				
	250	6,395,272	Deo et al.				
	251	6,403,630	Dannenberg et al.				
	252	6,458,356	Arakawa et al.				
	253	6,512,097	Marks et al.				

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	254	1,006,194	EPO				
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	256	444,181	EPO				
	257	494,135	EPO				
	258	502,812	EPO				
	259	554,441	EPO				
	260	656,367	EPO				
	261	WO 01/05425	PCT				
	262	WO 01/09187	PCT				
	263	WO 01/20033	PCT				
	264	WO 01/21192	PCT				
	265	WO 01/32155	PCT				
	266	WO 87/07646	PCT				
	267	WO 89/10412	PCT				
	268	WO 91/02062	PCT				

Examiner	Date Considered
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*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449		U.S. Dept. of Commerce Patent and Trademark Office		Atty Docket No. P1467K2	Serial No. 09/602,812	
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	269	WO 91/05264	18.04.91	PCT		
	270	WO 93/03741	04.03.93	PCT		
	271	WO 93/16186	19.08.93	PCT		
	272	WO 96/07321	14.03.96	PCT		
	273	WO 96/16673	06.06.96	PCT		
	274	WO 96/40789	19.12.96	PCT		
	275	WO 97/00271	03.01.97	PCT		
	276	WO 98/02463	22.01.98	PCT		
	277	WO 98/16628	23.04.98	PCT		
	278	WO 98/18489	07.05.98	PCT		
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	281	Agus et al., "Differential Anti-Tumor Effects of Targeting Distinct Epitopes of the Her-2/neu Extracellular Domain in Xenograft Models of Prostate Cancer." <u>Proceedings of the American Association for Cancer Research Annual Meeting (Abstract #4570) 41:719 (Mar 2000)</u>				
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293	James et al., "Phase II Trial of the bispecific antibody MDX-H210 (anti-HER2/NEU X anti-CD54) combined with GM-CSF in patients with advanced prostate and renal cell carcinomas that express HER2/NEU" <u>Proc. Annu. Meet. Soc. Clin. Oncol.</u> (Abstract No. 1681) 17:436a (1998)				
294	Kabat, <u>Sequences of Proteins of Immunological Interest</u> , US Dept of Health and Human Services, NIH, 5th edition, Bethesda, MD (1991)				
295	Knox et al., "Yttrium-90-labeled anti-CD20 monoclonal antibody therapy of recurrent B-cell lymphoma" <u>Clinical Cancer Research</u> 2(3):457-470 (Mar 1996)				
296	Medarex, Inc., "Medarex's HER-2 product show anti-cancer effects in phase II prostate and kidney studies" (company press release) (May 19, 1998)				
297	Myers et al., "Intracellular antibody mediated down-regulation of p185 ^{HER2} expression in malignant prostatic cells" <u>Proceedings of the American Association for Cancer Research Annual Meeting</u> (Abstract #2334) 37:342 (1996)				
298	Nagabhushan et al., "CWR22: The First Human Prostate Cancer Xenograft with Strongly Androgen-dependent and Relapsed Strains Both in Vivo and in Soft Agar" <u>Cancer Research</u> 56:3042-3046 (1996)				
299	Nagy et al., "Complexity of signal transduction mediated by ErbB2: clues to the potential of receptor-targeted cancer therapy" <u>Pathology Oncology Research</u> 5(4):255-271 (1999)				
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304	Stearns et al., "Workgroup 2: Human Xenograft Models of Prostate Cancer" <u>Prostate</u> 36:56-58 (1998)				
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ALH	236	2002/0076695	20.06.02	Ross, J.			
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Examiner

Anne L. Holleran

Date Considered

11/19/03

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09/602,812

Applicant

Adams et al.

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Anna C. Holleran

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